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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,631	09/27/2001	Carl Johan Friddle	LEX-0241-USA	2486

7590 02/05/2004

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EXAMINER	
NASHED, NASHAAT T	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 02/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/965,631	FRIDDLE ET AL.	
	Examiner	Art Unit	
	Nashaat T. Nashed	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6,8 and 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6,8 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The application and the claims have been amended as requested in the communication filed November 28, 2003.

The abstract of the disclosure is objected to because it does not describe the claimed invention or the content of the specification. Correction is required. See MPEP § 608.01(b).

In response to the above rejections, Applicants argue that numerous U. S. patents have an abstract identical to the present abstract.

Applicants' arguments filed 11/28/03 have been fully considered but they are not deemed to be persuasive. The issued U. S. Patents are presumed valid and it would be inappropriate for an examiner to comment on them, see 35 U. S. C. 282. Since cited patents have been issued and no longer under examination, they are of no relevance to the instant application, which is required to have an abstract describing the claimed invention.

Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary.

Complete revision of the content of the abstract is required on a separate sheet.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3, 6, 8, and 9 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility, for the reasons set forth in the prior Office action mailed June 28, 2003.

In response to the above rejections, Applicants argue that there is ample evidence supporting the applicants' assertion that the polypeptide of SEQ ID NO: 4 is a metalloproteinase. Applicants' assert that the knockout mice experiment indicates the polypeptide and its nucleic acid has a biological function and the nucleic acid and the

polypeptide can be utilized in the diagnosis and treatment arthritis, asthma, connective tissue, and other immune mediated disorder. Also, applicants argue that the observation of polymorphism in the nucleic acid sequence and polypeptide can be utilized in forensic and paternity analysis, and that the nucleic acid can be used in mapping chromosome.

Applicants' arguments filed 11/28/03 have been fully considered but they are not deemed to be persuasive. In rejecting the claims in the previous Office action, the examiner has no belief of any kind, and relied on basic scientific facts and the teaching of the specification. It appears that the applicants and the examiner are in agreement that the polypeptide of SEQ ID NO: 4 is probably a metalloproteinase. Applicants have made an assertion than the polypeptide is a metalloproteinase, which is neither a specific nor substantial utility. Also, the examiner agrees with the applicants about the many known utilities for metalloproteinases and their inhibitor, and the fact the polypeptide of SEQ ID NO: 4 must have a utility yet to be determined. Metalloproteinase family of enzymes encompass large number enzymes having diversified chemical and biological function, and thus, each member of the family has a specific and substantial utility of its own such as catalyzing the hydrolysis of a specific peptide bond, modulating blood pressure in mammals, or tissue and bone remodeling. The diverse utilities of the family members do not impart a utility on a new member. The specification has clearly failed to identify a single specific or substantial utility for the polypeptide of SEQ ID NO: 4 or the nucleic acid sequence of SEQ ID O: 3. While the knockout mice experiment indicates that disabling a gene results in an observed abnormality, the experiment have not established a link between any specific disease and either the nucleic acid or the polypeptide. Regarding polymorphism, most mammalian genes display some degree of polymorphism, and therefore, it is neither a specific nor substantial utility for the polypeptide or the nucleic acid. In addition, applicants have not shown any data to indicate such a marker can be used in forensic analysis. Similarly, chromosome mapping can be accomplished with any nucleic acid from the chromosome, and therefore, such a utility is neither specific nor substantial.

Applicants appear to argue that knowledge of the exact function or role of the presently claimed nucleic acid is not required for specific or substantial utility such as in tracking expression patterns using a DNA ship. Such a utility would apply to virtually every member of a general class of materials, such as any collection of proteins or DNA's, but is only potential use with respect to SEQ ID NO: 3 or 4. For this reason, such utilities are not specific and do not constitute a "well-established" utility. Further, because any potential diagnostic utility is not yet known and has not yet been disclosed, the utility is not substantial because it is not currently available in practical form. Moreover, use of the claimed polynucleotide in a DNA-array, such as in a toxicology screening, is only useful in the sense that the information that is gained from the array is dependent on the pattern derived from the array, and says nothing with regard to each individual member of the array. Again, this is a utility, which would apply to virtually every member of a general class of materials, such as any collection of proteins or

DNA's. Even, if the expression of Appellants' individual polynucleotide is affected by a test compound in an array for drug screening for example, the usefulness of the result of such screening would remain to be determined once done. This would constitute further experimentation on the material being claimed to identify or reasonably confirm a real world (i. e. substantial) use. The specification does not disclose any specific and substantial interpretation for the result, and none is known in the art.

On page 14 of applicants' response, last paragraph, the Applicants appear to disagree with the Patent Office policy and their interpretation of the law as they relate to the utility and written description guidelines. However, the Examination Guidelines represent the U. S. Patent and Trademark Office interpretation of the statutory requirements for a patentability under 35 U. S. C. § 101. The instant claims stand rejected under 35 U. S. C. § 101, not the guidelines.

The instant situation is directly analogous to that addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966), in which a novel compound structurally analogous to other compounds which were known to possess anti-tumor activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately apparent or fully disclosed "real world" utility. The court held that:

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. . . . a patent is not a hunting license. . . .[i]t is not a reward for the search, but compensation for its successful conclusion.

New claims 8 and 9 are included in this rejection because they sre drawn to the same subject matter.

Claims 1-4, 6, 8, and 9 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 2 and 3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention for the reasons set forth in the prior Office action, mailed June 28, 2003.

In response to the above rejection, Applicant amended claim 1 and argue the suitability of the rejection claim 1. They have not addressed the issue related to the rejection of claims 2 and 3.

Applicants' arguments filed 11/28/03 have been fully considered but they are not deemed to be persuasive. The rejection is no longer applicable to claim 1 since the nucleic acid of SEQ ID NO: 3 is fully described in the specification. Claim 2, however, is drawn to any nucleic acid sequence that hybridizes to SEQ ID NO: 3 or the complement thereof under some stringent condition. Such a genus of nucleic acid has not been described in the specification as indicated in the prior Office action. Applicant may obviate this rejection by including a function of the nucleic acid such as "encoding a metalloproteinase that catalyzes the hydrolysis of .....".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 2 and 3 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth in the prior Office action, mailed June 28, 2003.

In response to the above rejection, applicant amended the claim 2 by adding the word "highly" to stringent conditions, and argue that the phrase "highly stringent conditions" is defined in the specification on page 5, lines 1-8.

Applicants' arguments filed 11/28/03 have been fully considered but they are not deemed to be persuasive. While the specification exemplified the "highly stringent condition", it does not specify the condition as the one to be used. This rejection would be vacated, if the applicant amends the claim to include the specific "highly stringent condition described on page 5, lines 1-8.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the

requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 2 and 3 are rejected under 35 U.S.C. § 102(e) as being anticipated by WO 01/98468 [(Yue et al.), December 12, 2001, only the relevant part of the document enclosed].

In response to the above rejection, applicants amended the claims, and argue that the rejection is not applicable any more.

Applicants' arguments filed 11/28/03 have been fully considered but they are not deemed to be persuasive. The nucleic acid sequence of SEQ ID NO: 3 would be expected to hybridize to the nucleic acid of the prior art under some conditions which can be described "highly stringent conditions".

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-271-0934. The examiner can normally be reached Monday, Tuesday, Thursday, and Friday from 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph. D. can be reached on 571-272-0928. The fax phone numbers for this Group are (703) 305-3014 and (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nashaat T. Nashed, Ph. D.
Primary Examiner